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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,264	12/03/2001	Laurie H. Glimcher	HUI-040CP	2529
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LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			OUSPENSKI, ILIA I	
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DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/008,264	Applicant(s) GLIMCHER ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 50-59 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7,52 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8-12,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 10/25/2004, is acknowledged.

Claims 13 – 49 have been cancelled.

Claims 1 – 8 have been amended.

Claims 50 – 59 have been added.

Claims 1 – 12 and 50 – 59 are pending.

2. Applicant's election with traverse of Group I (Claims 1, 2, 4, 6, and 8 – 12, drawn to an isolated nucleic acid encoding human T-bet protein, as well as vectors, host cells, and methods of producing the protein) in the reply filed on 10/25/2004 is acknowledged. The traversal is on the ground(s) that the newly added claims 51 and 52 are allowable generic linking claims, as the human and murine sequences are expected to hybridize with each other, and that searches for human and murine nucleic acid molecules encoding T-bet proteins are allegedly coextensive.

3. As necessitated by Applicant's amendment, a new Restriction Requirement under 35 USC 121 is set forth herein:

Group I. Claims 1, 2, 4, 6, 8 – 12, 50 – 55, and 57 – 59, drawn to an isolated nucleic acid encoding human T-bet protein, as well as vectors, host cells, and methods of producing the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Group II. Claims 1, 3, 5, 7, 8 – 12, 50 – 52, 54, 56, and 57 drawn to an isolated nucleic acid encoding murine T-bet protein, as well as vectors, host cells, and methods of producing the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Groups I and II are different products. The claimed nucleic acids differ with respect to their structures and physicochemical properties and require non-coextensive searches, therefore each product is patentably distinct.

Claims 51 and 52 link inventions I and II. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 51 and 52. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. As detailed below, linking claim 51 was found not to be allowable. Therefore, claims 3, 5, 7, 52 and 56 (claims specific to non-elected Group II) are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 1, 2, 4, 6, 8 – 12, 50, 51, 53 – 55, and 57 – 59, as they read on the nucleic acids encoding human T-bet protein, are under consideration in the instant application.

5. Applicant requested clarification regarding the Restriction Requirement of claims 15, 17, and 19. Applicant's cancellation of these claims has rendered the issue moot.

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6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein.

Upon review of the instant application, it is noted that the sequences disclosed at least on pages 64 and 72 and in Figure 1 *are not accompanied by SEQ ID Numbers*. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is reminded to amend the specification and the claims accordingly.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

7. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

8. Applicant's claim for domestic priority under 35 U.S.C. §119(e) and §120 is acknowledged. The priority applications USSN 60/137,085 and PCT/US00/15345 appear to provide adequate support under 35 U.S.C. 112 for the subject matter of claims 1, 2, 4, 6, 8 – 12, 51, 53 – 55, and 57 – 59.

However, the priority applications fail to provide adequate support under 35 U.S.C. 112 for claim 50 of this application. Specifically, insufficient support was identified for the limitation of "IFN- γ production, Th1-associated cytokine production, and

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Th1 cell differentiation.” Consequently, the claim has been accorded the priority of the filing date of the instant application, i.e. 12/03/2001.

Should Applicant disagree with the Examiner’s factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

10. Applicant’s IDS, filed 08/01/2003, is acknowledged, and has been considered.

11. The use of trademarks has been noted in this application (e.g. SurfZAP™ on page 33). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

12. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g. on page 9. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

13. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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14. Claims 1, 51, 55, 58, and 59 are objected to because of the following informalities: sequence identifiers should have the following format "SEQ ID NO:X".

Appropriate correction is required.

15. It is noted that for examination purposes, the recitation of "complement" or "complementary" in the claims is interpreted to mean 100% complementarity over the full length of both sequences.

If Applicant disagrees with this interpretation, claims containing the recitations of "complement" or "complementary" are subject to rejection under 35 USC 112, first paragraph.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 8 – 12, 51, and 54 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 4, 6, 8 – 12, 51, 53, and 54 are indefinite in the recitation of "a T-box binding element in DNA," because the term is vague and indefinite. Although the specification mentions in several instances "T-box binding sites" (e.g. on pages 13 and 41), and provides an exemplary sequence of a consensus T-box binding site on page 72, characteristics of a broadly claimed "T-box binding element" are not defined. Thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

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B. Claim 50 is indefinite in the recitation of "activity selected from the group consisting of IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation," because it is ambiguous as to whether the claimed activity is directed to increasing or decreasing said production or differentiation. Thus the metes and bounds of the claimed Invention are not defined.

It is noted that for enablement purposes (see below) it is assumed that the claim is directed to increasing said activities.

C. Claim 50 is indefinite in the recitation of "Th1 cell differentiation," because the term is vague. It is unclear whether the claim is directed to T-bet activity to "redirect polarized Th2 cells into the Th1 pathway" (specification on page 39 second paragraph), to an initial commitment of T cells towards the Th1 pathway, or to some other aspect of complex and multifaceted process of T cell development. Thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

D. Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 4, 6, 8 – 12, 50, 53, 54, and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to specific passages in the specification for support for the newly added limitations. However, the specification does not appear to provide an adequate written description of certain limitations, as detailed below.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

A. Claims 4, 6, 8 – 12, 50, and 54 contain a recitation of “at least 95% nucleotide identity” to SEQ ID NO:1. While there is support in the specification for “at least 95% amino acid identity” (page 28 lines 23 – 24), the specification does not appear to provide an adequate written description of “at least 95% identity” as it applies to the nucleic acid sequence.

B. Claim 53 contains a recitation of “at least about 95% identity to the amino acid sequence of SEQ ID NO:2.” While the specification provides support for “at least 95% amino acid identity” (page 28 lines 23 – 24), the specification does not appear to provide an adequate written description of “at least about 95% identity” as it applies to the amino acid sequence.

C. Claim 50 contains a recitation of “Th1 cell differentiation.” Applicant points to page 39, lines 4 – 8 of the specification for support, which recites the property of T-bet proteins to “redirect polarized Th2 cells into the Th1 pathway.” The newly added limitation of “Th1 cell differentiation” is broader in scope than originally presented, as it

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encompasses other cellular processes, such as the initial commitment of cells towards the Th1 pathway.

D. Claim 59 includes a recitation of an isolated nucleic acid comprising nucleotides 1 – 900 of SEQ ID NO:1. While the specification provides support for fragments of SEQ ID NO:1 of at least about 900 nucleotides in length (page 37 lines 28 – 31), there appears to be insufficient direction to a fragment comprising specifically nucleotides 1 – 900 of said sequence.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

20. Claim 50 is rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a polypeptide that has the activity of [inducing] IFN- γ production in CD4⁺ cells, does not reasonably provide enablement for a broad recitation of a peptide that has the activity of [inducing] IFN- γ production.

It is noted that for enablement purposes, it is assumed that the claim is directed to inducing rather than suppressing IFN- γ production (see Rejection under 35 USC 112, second paragraph above).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses on pages 75 – 76 that in contrast to CD4⁺ cells, T-bet is not involved in controlling IFN- γ production in CD8⁺ T cells. Therefore, The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the types of cells in which IFN- γ can be induced by T-bet are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

21. Claims 55 and 57 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an isolated nucleic acid consisting of a fragment of at least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1 or complement thereof, or, alternatively, comprising the sequence of SEQ ID NO:1, does not reasonably provide enablement for an isolated nucleic acid comprising a fragment of at least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1 or complement thereof.

The specification does not appear to have provided sufficient guidance as to which subsequences of SEQ ID NO:1 would encode a protein which would share the activity of T-bet. Neither does the specification appear to have provided any working examples of any functional subsequences. Thus it would require undue experimentation of the skilled artisan to determine which subsequences of SEQ ID NO:1 would have the function of the full length molecule.

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The term "comprising" in claims 55 and 57 is open ended and extends the nucleic acid molecule to include additional non-disclosed sequences on either or both sides of the disclosed region. As the term "comprising" is applied to sequences other than full length T-bet sequences, there does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the various nucleic acids recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for binding to T-box binding element, or stimulating cytokine production or Th1 cell differentiation. Without detailed direction as to which nucleic acid sequences are essential to the function of the encoded polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of nucleic acid sequences encompassed by the instant claims would share the functional characteristics of T-bet.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention:

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claim 1, 2, 4, 6, 51, 53, 55, 58, and 59 are rejected under **35 U.S.C. 102(a)** as being anticipated by Yang (of record; cited as reference A5 on IDS filed 08/01/2003; see entire document).

Yang teaches a polypeptide which is 100% identical to the instantly claimed SEQ ID NO:2, and a nucleic acid sequence encoding said polypeptide which includes a region 100% identical to SEQ ID NO:1.

It is noted that the priority date of Yang is assumed to be the date of submission of the sequence to the EMBL/GenBank/DDBJ database, i.e. 09/17/1998.

As the sequence of the protein taught by Yang is identical to that of the instantly claimed protein, all of its functional properties are inherently the same.

The reference teaching thus anticipates the claimed invention.

24. Claim 50 is rejected under **35 U.S.C. 102(b)** as being anticipated by Yang (of record; cited as reference A5 on IDS filed 08/01/2003; see entire document).

As detailed above, Yang teaches a polypeptide which is 100% identical to the instantly claimed SEQ ID NO:2, and a nucleic acid sequence encoding said polypeptide which includes a region 100% identical to SEQ ID NO:1. As the sequence of the protein taught by Yang is identical to that of the instantly claimed protein, all of its functional properties are inherently the same.

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Since claim 50 has been accorded the priority date of the instant application, i.e. 12/03/2001, the rejection is set forth under 35 U.S.C. 102(b) rather than 102(a).

The reference teaching thus anticipates the claimed invention.

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 8 – 12 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Kishimoto et al. (US Pat. No. 5,844,082; see entire document) in view of Yang (of record; reference A5 on IDS filed 08/01/2003; see entire document).

Kishimoto et al. teach nucleic acids encoding a transcription factor, as well as expression vectors and host cells comprising said nucleic acids, and methods of producing the transcription factor by culturing host cells (see entire document, in

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particular, column 5 line 55 – column 6 line 18). Kishimoto et al. further teach that expressing a transcription factor may be useful for treatment of diseases (see entire document, in particular, e.g. the Abstract). Kishimoto et al. evidence that such methods were routine at the time the invention was made, as evidenced by the phrase “by each method commonly used” when referring to introduction of a vector into host cells (column 6 line 3).

Kishimoto et al. do not specifically teach vectors, host cells, or methods of expression of a T-bet transcription factor.

Yang has been discussed supra, and teaches a human transcription factor which is 100% identical to the instantly claimed T-bet transcription factor of SEQ ID NO:2, and a nucleic acid sequence encoding said transcription factor which includes a region 100% identical to instantly claimed SEQ ID NO:1.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Kishimoto et al. to the transcription factor taught by Yang, to arrive at the instantly claimed Invention.

One of ordinary skill in the art at the time the invention was made would have been motivated to express the T-bet transcription factor of the instant Invention by placing the respective nucleic acids into an expression vector and further into a host cell, and to express the protein by culturing the cells, because Kishimoto et al. teach that expressing a transcription factor may be useful for treatment of diseases (see entire document, in particular, e.g. the Abstract). Furthermore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success, because these methods were routinely used at the time, as evidenced by Kishimoto et al. in the phrase “by each method commonly used” when referring to introduction of a vector into host cells (column 6 line 3).

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Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 1, 2, 4, 6, 8 – 12, 50, 51, 53 – 55, and 57 – 59 are provisionally rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claims 1, 11, 12, 14, 19, and 22 of copending Application USSN 10/309,747, published as US Pat. Pub. No. 2003/0186377.

Claims 1, 11, 12, 14, 19, and 22 of USSN 10/309,747 are drawn to a nucleic acid encoding a T-bet polypeptide, a vector comprising said nucleic acid, and a method of producing said polypeptide by culturing a host cell comprising said vector.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same nucleic acids encoding a T-bet protein, as well as vectors and methods of producing the polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Conclusion: no claim is allowed.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644
January 12, 2005

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PRIMARY EXAMINER
TCH Chan 1600
1/19/05